

01/236,724

ATTORNEY DOCKET NO. : 061635-0007

U.S. Patent No. 4,937,078

Page 1

DAE  
JFW



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Number 4,937,078 )  
)  
Granted: June 26, 1990 )  
)  
Patentees: Michael MEZEI and Adrienn )  
GESZTES )  
)  
Assignee: Lipoderm Pharmaceuticals Ltd. )  
)  
For: LIPOSOMAL LOCAL )  
ANESTHETIC AND ANALGESIC )  
PRODUCTS )  
)

Docket No.: 04E-0389

Commissioner for Patents  
U.S. Patent and Trademark Office  
Customer Window, **Mail Stop Patent Ext.**  
Randolph Building  
Alexandria, VA 22314

Date: December 1, 2005

**REQUEST FOR CORRECTION OF ASSIGNEE IN PENDING APPLICATION  
FOR EXTENSION OF PATENT TERM PURSUANT TO 35 U.S.C. § 156**

Dear Sir:

A Request for Extension of Patent Term Pursuant to 35 U.S.C. § 156 was submitted to the United States Patent and Trademark Office on July 7, 2004 requesting extension of patent term for United States patent number 4,937,078 ("Request"). It has recently come to the attention of current assignee, Lipoderm Pharmaceuticals Ltd., that the Request was submitted in the name of the former assignee, Mezei Associates, Ltd.

In a letter, dated April 8, 2005 from Jane A Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research, Ms. Axelrad advised that NADA

number 141-186, for the animal drug product Surpass (diclofenac sodium) was approved on May 13, 2004 and the submission of the of the patent term extension application on June [sic] 7, 2004 was timely within the meaning of 35 U.S.C. § 156. (*See* April 8, 2005 Letter Attached as Exhibit A).

In a letter, dated July 18, 2005, from Karin Ferriter, Senior Legal Advisor, Office of Patent Legal Administration to Ms. Axelrad, Ms. Ferriter acknowledged that United States patent number 4,937,078 was eligible for patent term restoration and requested Ms. Axelrad to determine the applicable regulatory review period. (*See* July 18, 2005 Letter attached as Exhibit B).

Applicant, Lipoderm Pharmaceuticals Ltd., a corporation created and existing under the Laws of Canada, represents that it is the owner of the entire interest in and to United States Patent Number 4,937,078 for LIPOSOMAL LOCAL ANESTHETIC AND ANALGESIC PRODUCTS, granted to Michael MEZEI and Adrienn GESZTES on June 26, 1990, by virtue of an assignment from Mezei Associates Ltd. to Lipoderm Pharmaceuticals Ltd., dated April 17, 1997 ("Lipoderm Assignment"). The Lipoderm Assignment was submitted for recordation by facsimile to the U.S. Patent and Trademark Office Assignment Recordation Department on November 30, 2005. A copy of the Assignment, the Recordation Form Cover Sheet, the facsimile cover sheet, and the facsimile transmittal acknowledging submission are attached as Exhibit C.

A Grant of Power of Attorney, authorizing the registered practitioners of Morgan, Lewis & Bockius LLP associated with customer number 009629, to act on behalf of Lipoderm Pharmaceuticals Ltd. for the purpose of obtaining a patent term extension for United States patent number 4,937,078 is attached as Exhibit D.

In accordance with the Grant of Power of Attorney, please address all inquiries and correspondence relating to this application for patent term extension to:

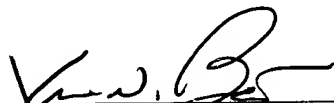
Victor N. Balancia  
Morgan, Lewis & Bockius LLP  
1111 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004  
Telephone: 202-739-5667  
Facsimile: 202-739-3001

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this Request including fees due and any required extension of time fees, or credit any overpayment to Deposit Account 50-0310.

Respectfully Submitted,  
**Morgan, Lewis & Bockius LLP**

Date: December 1, 2005

Morgan Lewis & Bockius LLP  
Customer No. **09629**  
1111 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004  
Tel. No.: 202-739-3000

  
\_\_\_\_\_  
Victor N. Balancia  
Registration No. 31,231  
Tel. No.: (202) 739-5656  
Fax No.: (202) 739-3001



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

VNB  
DLF

Food and Drug Administration  
Rockville MD 20857

Re: Surpass  
Docket No. 04E-0389

APR 8 2005

61635-5007

The Honorable Jon Dudas  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office  
Box Pat. Ext.  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 4,937,078 filed by Mezei Associates, Ltd. under 35 U.S.C. § 156. The animal drug product claimed by the patent is Surpass (diclofenac sodium), which was assigned NADA No. 141-186.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F.2d 392 (Fed. Cir. 1990).

The NADA was approved on May 13, 2004, which makes the submission of the patent term extension application on June 7, 2004, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

  
Jane A. Axelrad

Associate Director for Policy  
Center for Drug Evaluation and Research

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APR 1 2005

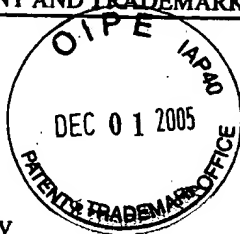
MORGAN, LEWIS & BOCKIUS LLP

cc: ~~Paul E. Dietze~~ VMBANCIA  
Morgan, Lewis & Bockius, LLP  
1111 Pennsylvania Ave., NW  
Washington, DC 20004



UNITED STATES PATENT AND TRADEMARK OFFICE

JUL 18 2005



VVB/DLF  
Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
www.uspto.gov

Office of Regulatory Policy  
HFD - 13  
5600 Fishers Lane,  
Rockville, MD 20857

Attention: Claudia Grillo

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 4,937,078. The application was filed on June 7, 2004, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (571)272-7744 (telephone) or (571)273-7744 (facsimile).

Karin Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Paul E. Dietze  
Morgan, Lewis & Bockius, LLP  
1111 Pennsylvania Ave., NW  
Washington DC 20004

RE: Surpass® (diclofenac sodium)  
Docket No. 04E-0389

RECEIVED

JUL 21 2005

MORGAN, LEWIS & BOCKIUS LLP

DOCKETED

By BIC Date 7/21/05



- 4 -

Schedule "A"

ASSIGNMENT

The undersigned, MEZEL ASSOCIATES LTD. whose full post office address is P.O. Box 2255 Halifax, in consideration of the sum of \$1.00 and other good and valuable consideration, the sufficiency and receipt of which is hereby acknowledged, does hereby sell, assign and transfer to LIPODERM PHARMACEUTICALS LTD. whose full post office address is P.O. Box 2255, Halifax, Nova Scotia, Canada, B3J 3C8, its successors and assigns forever, all my right, title and interest in, to and under the following patents:

1. United States of America Letters Patent No. 4,761,288 granted on the 2nd day of August, 1988;
2. United States of America Letters Patent No. 4,897,269 granted on the 30th day of January, 1990;
3. United States of America Letters Patent No. 4,937,078 granted on the 26th day of June, 1990;
4. European Letters Patent No. 0 177 223 B1 granted on the 28th day of February, 1990;
5. Japanese Letters Patent No. 015467 granted in 1994;

the same to be held and enjoyed by LIPODERM PHARMACEUTICALS LTD. to the full end of the term for which the said Letters Patent are granted, as fully and entirely as the same could have been held and enjoyed by MEZEL ASSOCIATES LTD. if this assignment and sale had not been made.

EXECUTED AT NSX this 17 day of April, 1997.

SIGNED, SEALED AND DELIVERED  
in the presence of:

Katherine Mezei  
Witness

MEZEL ASSOCIATES LIMITED

Per: Michael Mezei c/s  
MICHAEL MEZEL, President

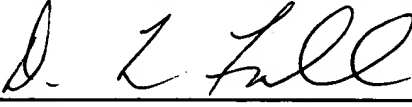
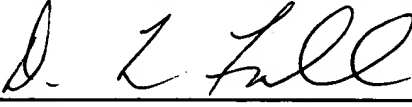
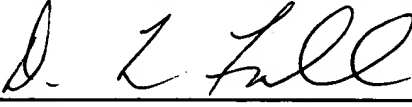
(ASSIGN)

RECORDATION FORM COVER SHEET  
PATENTS ONLY

Attorney Docket Number -061635-0007

Mail Stop Assignment Recordation Services  
Director of the United States Patent and Trademark Office  
Randolph Building, Customer Window  
Alexandria, VA 22314

Please record the attached original documents or copy thereof.

<b>1. Name of conveying party(ies):</b> <b>MEZEI ASSOCIATES LTD.</b>		<b>2. Name and address of receiving party(ies):</b> Name: LIPODERM PHARMACEUTICALS LTD. Address: P.O. Box 2255, Halifax, Nova Scotia									
Additional name(s) of conveying party(ies) attached? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Country (if other than USA): Canada B3J 3C8									
<b>3. Nature of conveyance:</b> <input checked="" type="checkbox"/> Assignment Merger Security Agreement Change of Name Other											
Execution Date: <u>April 17 1997</u>											
<b>4. Application number(s) or patent number(s):</b> If this document is being filed together with a new application, the execution date of the application is: A. Patent Application No.(s) _____ B. Patent No. 4,937,078 Additional numbers attached? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No											
<b>5. Name and address of party to whom correspondence concerning document should be mailed:</b> Morgan, Lewis & Bockius LLP 1111 Pennsylvania Avenue, N.W. Washington, DC 20004		<b>6. Number of applications and patents involved:</b> <u>1</u>									
		<b>7. Total fee (37 CFR 3.41):</b> .....\$40.00 Please charge to the deposit account listed in Section 8.									
		<b>8. Deposit account number:</b> <u>50-0310</u>									
<b>DO NOT USE THIS SPACE</b>											
<b>9. Statement and signature.</b>  <i>To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.</i>  <table border="0" style="width: 100%;"><tr><td style="width: 30%;"><u>Dean L. Fanelli</u></td><td style="width: 15%; text-align: center;"><u>48,907</u></td><td style="width: 40%; text-align: center;"></td><td style="width: 15%; text-align: center;"><u>November 30, 2005</u></td></tr><tr><td>Name of Person Signing</td><td>Reg. No.</td><td>Signature</td><td>Date</td></tr></table>				<u>Dean L. Fanelli</u>	<u>48,907</u>		<u>November 30, 2005</u>	Name of Person Signing	Reg. No.	Signature	Date
<u>Dean L. Fanelli</u>	<u>48,907</u>		<u>November 30, 2005</u>								
Name of Person Signing	Reg. No.	Signature	Date								
Total number of pages including cover sheet:			2								

Mail documents to be recorded with required cover sheet information to:  
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Director of the United States Patent and Trademark Office  
Randolph Building, Customer Window  
Alexandria, VA 22314

Morgan, Lewis & Bockius LLP  
1111 Pennsylvania Avenue NW  
Washington, D.C. 20004  
TEL: 202.739.3000  
FAX: 202.739.3001  
eFax: 877.432.9652  
www.morganlewis.com

Morgan Lewis  
C O U N S E L O R S   A T   L A W

FAXED

SEND TO

Name: Assignment Recordation Services Firm: U.S. Patent and Trademark Office  
FAX #: 571-273-0140 Telephone #:

FROM

Name: Dean L. Fanelli, Ph.D. Floor: 3rd  
Operator Sending: Telephone #: (202) 739-5656  
FAX #: (202) 739-3001 Date Sent: November 30, 2005 Number of Pages: 3  
(including cover page)

FAX MESSAGE

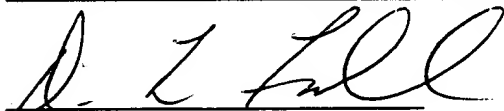
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COMMENTS

U.S. Patent No. 4,937,078  
U.S. Patent Application No. 08/236,724  
Issued: June 26, 1990  
Inventors: Michael Mezei and Adrienn Gesztes  
Filed: August 26, 1988  
Title: Liposomal Local Anesthetic and Analgesic Products  
Attorney Docket: 061635-0007

Certificate of Transmission Under 37 C.F.R. 1.8

I hereby certify that the attached Recordation Form Cover Sheet and Assignment document are being transmitted via facsimile to the Assignment Recordation Services at the U.S. Patent Office on Thursday, September 30, 2004. Applicants request that the attached Assignment be recorded by the U.S. Patent Office.



Dean L. Fanelli  
Registration No. 48,907



JOB #539

DATE	TIME	TO/FROM	MODE	MIN/SEC	PGS	STATUS
001 11/30	13:05	15665003#15712730140#	EC--S	01' 02"	003	OK

Morgan, Lewis & Bockius LLP  
1111 Pennsylvania Avenue NW  
Washington, D.C. 20004  
TEL: 202.739.3000  
FAX: 202.739.3001  
eFax: 877.432.9652  
www.morganlewis.com

**Morgan Lewis**  
COUNSELORS AT LAW

**SEND TO**

Name: Assignment Recordation  
Services  
FAX #: 571-273-0140

Firm: U.S. Patent and Trademark  
Office  
Telephone #:

**FROM**

Name: Dean L. Fanelli, Ph.D.  
Operator Sending: WB

Floor: 3rd  
Telephone #: (202) 739-5656

FAX #: (202) 739-3001

Date Sent: November 30, 2005  
Number of Pages: 3  
(including cover page)

**FAX MESSAGE**

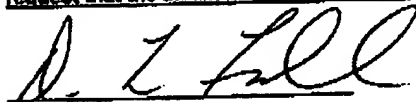
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**COMMENTS**

U.S. Patent No. 4,937,078  
U.S. Patent Application No. 06/236,724  
Issued: June 26, 1990  
Inventors: Michael Mazel and Adrienn Gasztes  
Filed: August 26, 1988  
Title: Liposomal Local Anesthetic and Analgesic Products  
Attorney Docket: 061638-0007

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Dean L. Fanelli  
Registration No. 48,907

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

United States Patent No.: 4,937,078

Issued: June 26, 1990

Inventors: Michael Mezei and Adrienn Gesztes

For: LIPOSOMAL LOCAL ANESTHETIC  
AND ANALGESIC PRODUCTS

Assistant Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**GRANT OF POWER OF ATTORNEY**

The undersigned:

**LIPODERM PHARMACEUTICALS LTD.**, Nova Scotia, Canada, a corporation of  
Canada hereby appoint(s) the following persons as agent:

BALANCIA, Victor; BEARDELL, Louis W.; BIRD, Donald J.; GAYBRICK, Robert J.; GOLUB, Daniel H.; GOODWYN, R. Tyler; KOKULIS, Paul N.; MCCUTCHEON, Nathan W.; ZELE, John D.; BOSWELL, Mary Jane; BRETSCHER, Carl P.; HAYDEN, Christopher G.; WEIMAR, Elizabeth C.; ANTONELLI, Arthur; BASSON, Kent E.; DAVIS, Kenneth, J.; FANELLI, Dean L.; GOODELL, Robert J.; HALLIDAY, Christopher I.; HOLLINGSHEAD, Robert J.; KOENIGBAUER, Fabian M.; LOWEN, Gregory T.; MAURER, Eric J.; MCLEOD, Bonnie W.; NELSON, Thomas E.; PARK, Collin W.; REED, James L.; SMYTH, Robert J.; SULLIVAN, Mark J.; TAYLOR, Todd P.; TENG, Sally P.; WEISBERG, Alison; all of MORGAN, LEWIS & BOCKIUS LLP, 1111 Pennsylvania Avenue, NW, Washington, DC 20004 United States of America

for the purpose of obtaining a patent term extension for United States patent no. 4,937,078. Assignee further directs that all correspondence for this matter be addressed to the Customer Number given below:

**Customer Number: 009629**

Please direct all inquiries to:

**Victor N. Balancia  
Morgan, Lewis & Bockius LLP  
1111 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004  
Telephone: (202) 739-5667**

The undersigned certifies that he is empowered to act on behalf of **LIPODERM PHARMACEUTICALS LTD.**, in this matter. The undersigned hereby certifies that **LIPODERM PHARMACEUTICALS LTD.**, has the entire right, title and interest in the above-identified United States patent by virtue of an assignment dated April 17, 1997 from Michael Mezei President of **MEZEI ASSOCIATES LTD.**

Signature for Applicant: \_\_\_\_\_

Title: \_\_\_\_\_

Address: \_\_\_\_\_

1507 Grant Ave

Cornwall, ON

K8J-1Z6 CANADA

Date: \_\_\_\_\_

Nov 15 / 05